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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,626 | 07/25/2002 | Cynthia Green | 15966-562NALT | 3311 |

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| EXAMINER | |
|---|---|
| OUSPENSKI, ILIA I | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/069,626 | GREEN ET AL. | |
| | Examiner | Art Unit | |
| | ILIA OUSPENSKI | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19 and 21-26* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1 – 26 are pending.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. It is noted that claim 20 is directed to the "use" of a therapeutic. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore, claim 20 has been withdrawn from consideration as being drawn to non-statutory subject matter. If claim 20 is amended to recite statutory subject matter, the amended claim may be rejoined with the appropriate invention Group as set forth below.

4. It is noted that the claims are directed to nucleic acids of SEQ ID NOS:1, 3, and 5, encoding polypeptides of SEQ ID NOS:2, 4, and 6, respectively. As detailed below, these nucleic acid molecules do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features that defines the contribution over the prior. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

It is further noted that claim 6 includes a recitation of nucleic acids of SEQ ID NOS: 7 – 12, which constitute fragments of SEQ ID NOS:1, 3, and 5. Each of these

fragments, although not specifically listed below, is grouped with the corresponding full-length sequence of SEQ ID NOS:1, 3, or 5.

It is further noted that claims 17 and 18 include recitations of a nucleic acid, a polypeptide, and an antibody. These molecules do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features that defines the contribution over the prior. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

***Restriction Requirement***

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1 – 9, 13, and 18 – 19, drawn to an isolated nucleic acid molecule of SEQ ID NO:1, or encoding a polypeptide of SEQ ID NO:2, as well as a vector, a method of producing a polypeptide by culturing host cells, and a composition comprising the nucleic acid, and a kit comprising the composition.

II. Claims 1 – 9, 13, and 18 – 19, drawn to an isolated nucleic acid molecule of SEQ ID NO:3, or encoding a polypeptide of SEQ ID NO:4, as well as a vector, a method of producing a polypeptide by culturing host cells, and a composition comprising the nucleic acid, and a kit comprising the composition.

III. Claims 1 – 9, 13, and 18 – 19, drawn to an isolated nucleic acid molecule of SEQ ID NO:5, or encoding a polypeptide of SEQ ID NO:6, as well as a vector, a method of producing a polypeptide by culturing host cells, and a composition comprising the nucleic acid, and a kit comprising the composition.

IV. Claims 10 - 11 and 18 - 19, drawn to a polypeptide of SEQ ID NO:2, and a composition comprising the polypeptide, and a kit comprising the composition.

V. Claims 10 - 11 and 18 - 19, drawn to a polypeptide of SEQ ID NO:4, and a composition comprising the polypeptide, and a kit comprising the composition.

VI. Claims 10 - 11 and 18 - 19, drawn to a polypeptide of SEQ ID NO:6, and a composition comprising the polypeptide, and a kit comprising the composition.

VII. Claims 12 and 18 - 19, drawn to an antibody to a polypeptide of SEQ ID NO:2, and a composition comprising the antibody, and a kit comprising the composition.

VIII. Claims 12 and 18 - 19, drawn to an antibody to a polypeptide of SEQ ID NO:4, and a composition comprising the antibody, and a kit comprising the composition.

IX. Claims 12 and 18 - 19, drawn to an antibody to a polypeptide of SEQ ID NO:6, and a composition comprising the antibody, and a kit comprising the composition.

X. Claim 14, drawn to a method of detecting a polypeptide of SEQ ID NO:2.

XI. Claim 14, drawn to a method of detecting a polypeptide of SEQ ID NO:4.

XII. Claim 14, drawn to a method of detecting a polypeptide of SEQ ID NO:6.

XIII. Claim 15, drawn to a method of detecting a nucleic acid molecule of SEQ ID NO:1.

XIV. Claim 15, drawn to a method of detecting a nucleic acid molecule of SEQ ID NO:3.

XV. Claim 15, drawn to a method of detecting a nucleic acid molecule of SEQ ID NO:5.

XVI. Claim 16, drawn to a method of modulating the activity of a polypeptide of SEQ ID NO:2.

XVII. Claim 16, drawn to a method of modulating the activity of a polypeptide of SEQ ID NO:4.

XVIII. Claim 16, drawn to a method of modulating the activity of a polypeptide of SEQ ID NO:6.

XIX. Claim 17, drawn to a method of treating or preventing a disorder by administering a nucleic acid of SEQ ID NO:1.

XX. Claim 17, drawn to a method of treating or preventing a disorder by administering a nucleic acid of SEQ ID NO:3.

XXI. Claim 17, drawn to a method of treating or preventing a disorder by administering a nucleic acid of SEQ ID NO:5.

XXII. Claims 17 and 25, drawn to a method of treating or preventing a disorder by administering a polypeptide of SEQ ID NO:2.

XXIII. Claims 17 and 25, drawn to a method of treating or preventing a disorder by administering a polypeptide of SEQ ID NO:4.

XXIV. Claims 17 and 25, drawn to a method of treating or preventing a disorder by administering a polypeptide of SEQ ID NO:6.

XXV. Claims 17 and 26, drawn to a method of treating or preventing a disorder by administering a an antibody to polypeptide of SEQ ID NO:2.

XXVI. Claims 17 and 26, drawn to a method of treating or preventing a disorder by administering a an antibody to polypeptide of SEQ ID NO:4.

XXVII. Claims 17 and 26, drawn to a method of treating or preventing a disorder by administering a an antibody to polypeptide of SEQ ID NO:6.

XXVIII. Claims 21 – 22, drawn to a method for screening for a modulator of an immune disorder by administering a test compound to an animal which recombinantly expresses a polypeptide of SEQ ID NO:2.

XXIX. Claims 21 – 22, drawn to a method for screening for a modulator of an immune disorder by administering a test compound to an animal which recombinantly expresses a polypeptide of SEQ ID NO:4.

XXX. Claims 21 – 22, drawn to a method for screening for a modulator of an immune disorder by administering a test compound to an animal which recombinantly expresses a polypeptide of SEQ ID NO:6.

XXXI. Claim 23, drawn to a method for determining the presence of a disease by measuring the amount of a polypeptide of SEQ ID NO:2.

XXXII. Claim 23, drawn to a method for determining the presence of a disease by measuring the amount of a polypeptide of SEQ ID NO:4.

XXXIII. Claim 23, drawn to a method for determining the presence of a disease by measuring the amount of a polypeptide of SEQ ID NO:6.

XXXIV. Claim 24, drawn to a method for determining the presence of a disease by measuring the amount of a nucleic acid of SEQ ID NO:1.

XXXV. Claim 24, drawn to a method for determining the presence of a disease by measuring the amount of a nucleic acid of SEQ ID NO:3.

XXXVI. Claim 24, drawn to a method for determining the presence of a disease by measuring the amount of a nucleic acid of SEQ ID NO:5.

7. The inventions listed as Groups I – XXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of WO 1999/046281.

WO 1999/046281 teaches and claims an isolated nucleic acid molecule (PRO352, SEQ ID NO:136) which is identical in sequence to the instantly claimed SEQ ID NO:5, encoding the instantly claimed polypeptide of SEQ ID NO:6 (see page 13, page 114, claims 2 – 3, and figure 50; due to the size of the document only the relevant pages are provided with this Office Action). It is noted that priority applications 60/152,383 and 60/172,909 fail to provide support for SEQ ID NOS:5 and 6; therefore, the teachings of the WO 1999/046281 document constitute prior art regarding the instantly claimed SEQ ID NOS:5 and 6.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. It is noted that claims 17 and 25 – 26 include recitations of an "immune response-associated disorder" and "pathological state," while the specification at least on pages 72 – 81 discloses a number of specific disorders and pathological states. These conditions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In the event that specific conditions are introduced into the claims during prosecution, additional restriction and/or species election may be required.

10. It is further noted that claims 14 and 16 include a recitation a "compound that binds to the polypeptide" of the invention, while e.g. claim 12 includes a recitation of an antibody to the polypeptide. The specification discloses at least on page 48 examples of other compounds which may bind the polypeptides of the invention, such as peptidomimetics and small molecules. These types of compounds are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In the event that specific types of compounds are introduced into the claims during prosecution, additional restriction and/or species election may be required.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
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Art Unit 1644

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3/3/05

March 2, 2005